REMARKS

Filed concurrently herewith is a request for a one-month extension of time, which extends the shortened statutory period for response to April 4, 2004 (Sunday). Accordingly, it is respectfully submitted that Applicants' response is being timely filed.

The Official Action dated December 4, 2003 has been received and its contents noted. Prior to this Amendment, claims 14-29 and 37-41 were pending in the present application for consideration. By this Amendment, 14 has been amended, and claims 22-26 and 37-41 have been canceled. Accordingly, claims 14-21 are pending for consideration, of which claim 14 is independent.

Referring now to the detailed Office Action, claims 14-29 and 37-41 stand rejected under 35 U.S.C. §102(b) as anticipated by Trivedi (U.S. Patent No. 4,683,223 – hereafter Trivedi). In response to the rejection, Applicants have amended claim 14, as shown above. Support for the amendment of claim 14 can be found on, e.g., line 18, page 32 to line 2, page 35 of the specification.

In the interest of expediting the prosecution of this application, Applicants have cancelled claims 22-26 and 37-41 without prejudice or disclaimer to the subject matter disclosed therein. Applicants reserve the right to file a divisional application to claim the subject matter in the cancelled claims in the future, as necessary.

As disclosed in the specification, the concentration (X) of the elements to be quantified in the biological sample may be determined by an equation 1 as a function of the concentration (Y) of the elements to be quantified in the sample for quantification prepared by the above-described method and the dilution ratio (a) of the biological sample in the sample for quantification.

$$X = aY \qquad \text{(eq. 1)}$$

In the present invention, the dilution ratio can be determined as described below.

$$C2 = Ml/(V1+V2) \qquad \text{(eq. 2)}$$

where, C2 is the concentration of the indicating material in the sample for quantification, V1 is the volume of the aqueous solution used for preparing the sample for quantification, Ml is the amount of the indication material used therefor, and V2 is the volume of the biological sample used therefor (note: V2 is not measured).

On the other hand, the concentration C1 of the indicating material in the aqueous solution (i.e., the reference solution) used for preparing the sample for quantification can be represented as:

$$C1 = M1/V1 \qquad \text{(eq. 3)}$$

It is to be noted that in the method for preparing the sample for quantification from the biological sample, the reference solution is a solution prepared without using the biological sample.

Since the dilution ratio (a) of the unknown volume of biological sample in the sample for quantification can be represented as:

$$a = (V1 + V2)/V2 \qquad \text{(eq. 4)}$$

the dilution ratio (a) may be rewritten by using C1 and C2 as shown in equation 5.

$$\text{Dilution ratio (a)} = (V1 + V2)/V2 = C1/(C1 - C2) \qquad \text{(eq. 5)}$$

Herein, the concentrations C1 and C2 of the indicating material can be determined by: measuring an absorptivity when the indicating material is a pigment or a chromogen; by measuring a light emitting intensity when the indicating material is a light emitting material; or by measuring a fluorescence intensity when the indicating material is a fluorescent material. When the indicating material is quantified by the absorptivity, since the concentration is in proportion to the absorptivity, they may be written as:

$$C2/C1 = E2/E1 \qquad \text{(eq. 6)}$$

where, C1 and El are the concentration and the absorptivity of the reference solution, and C2 and E2 are those of the sample for quantification, respectively. Accordingly, the dilution ratio can be determined by an equation rewritten as:

Dilution ratio (a) =C1/ (C1-C2) =El/(El - E2) (eq. 7)

As described above, the dilution ratio can be calculated based on the C1 and C2 values or the El and E2 values. It is to be noted that although the C1 or the El value may be set in advance to a known value and since they may be quantified by using the newly prepared solution, the amount of the indicating material in the reference solution may not be set, in advance, to a known value. That is, in accordance with the present invention, a volume of a solution is to be mixed directly with the biological sample. If this solution contains the indicating material, an amount or a concentration of the indicating material and a volume of the solution containing the indicating material, and an amount or a concentration of the indicating material used for preparing the sample for quantification, each of them need not be known and can be arbitrary, as long as they are constant.

The method for quantifying the indicating material may be any method as long as it can quantify the concentration of the indicating material. When the indicating material is a pigment, the absorptivity of the sample for quantification itself can be quantified. In other cases, a specified volume of sample is taken out of the sample for quantification and the concentration thereof is quantified by a quantifying method for the indicating material to be quantified. Upon quantification, when the absorptivity is used therefor, the value of absorptivity can be used directly without converting it to the concentration of the indicating material.

As set forth above, the quantification of a specific element contained in a biological sample prepared by Applicants' claimed method can be accomplished without knowing the volume of the biological sample.

Applicants respectfully assert that Trivedi, directed in part to an anti-inflammatory assay (see column 13) fails to teach or suggest each and every step as now set forth in independent claim 14. For example, Trivedi at least does not disclose the steps of:

collecting volume of biological sample without quantifying the volume thereof to mix with a specified volume of an aqueous solution,

measuring an absorptivity of an indicating material in the aqueous solution,

measuring an absorptivity of the indicating material in the collected biological sample mixed with the specified volume of the aqueous solution,

calculating a dilution ratio of the biological sample using the absorptivity of the indicating material in the specified volume of the aqueous solution and the absorptivity of the indicating material in said biological sample mixed with the specified volume of the aqueous solution,

measuring an absorptivity of said element in the biological sample mixed with the specified volume of aqueous solution, and

obtaining a quantified value of said element in the biological sample using the measured absorptivity of said element and the calculated dilution ratio, as recited in amended claim 14.

Consequently, since each and every feature of the present claims is not taught (and is not inherent) in the teachings of Trivedi, as is required by MPEP Chapter 2131 in order to establish anticipation, the rejection of claims 14-21 under 35 U.S.C. §102(b), as anticipated by Trivedi is improper. If this rejection is maintained, Applicants request that each and every claim feature be identified and references to the Trivedi patent be included for each claim feature.

In view of the foregoing, it is respectfully requested that the 35 U.S.C. §102(b) rejection of record be reconsidered and withdrawn by the Examiner, that claims 14-21 be allowed and that the application be passed to issue.

Should the Examiner believe a conference would be of benefit in expediting the prosecution of the instant application, he is hereby invited to telephone counsel to arrange such a conference.

Respectfully submitted,

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